REMARKS

Claims 1 - 16 were pending in the application. As a result of election with traversal claims 13 - 16 were withdrawn from consideration and are hereby canceled without prejudice to applicant's rights to the matter claimed therein. Claims 1 - 12 and 17 - 22 are now pending in the application. Claims 3 - 8 are currently amended. Claims 17 - 22 are new. Claims 1, 2 and 9 - 12 are original. A marked up version of the amended claims along with clean copy of other claims currently pending in the application is given above.

No new matter has been introduced by virtue of the amendments made herein. Accordingly, applicants respectfully request their entry. In view of the amendments made herein and the remarks below, applicants respectfully request reconsideration and withdrawal of the rejection set forth in the March 14, 2003 Office Action.

Claim Objections

The Examiner objected to claim 8 because of informalities due to the employment of the parenthetical expressions ("the X carbocyclic group") and the ("the Y carbocyclic group"). To facilitate prosecution, and for the sake of clarity, these terms have been amended to recite: "...herein termed "the X carbocyclic group"..." and "...herein termed "the Y carbocyclic group"..." Applicant respectfully requests that the Examiner withdraw the objection to claim 8.

Rejection For Obviousness-Type Double Patenting

The Examiner rejected claims 1 - 12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 12, and 14 of US Patent No.6,410,550 in view of Albaugh et al. (WO 99/10347). The Examiner concedes that US Patent 6,410,550 "...does not expressly claim that [sic] the composition additionally comprising GABAA."

Applicant submits that instant claim 1 recites: "A pharmaceutical composition comprising a combination of an inverse agonist of the $GABA_A$ $\alpha 5$ receptor subtype; a nicotine receptor partial agonist (NRPA), estrogen, selective estrogen modulators, or vitamin E; and a pharmaceutically acceptable carrier."

Applicant further submits that neither of the cited references teach suggest or hint that they be combined to form a pharmaceutical composition comprising both $GABA_A$ and NRPA, let alone the pharmaceutical composition of claim 1 which in addition comprises "...estrogen, selective estrogen modulators, or vitamin E..." and is therefore not a mere combination of the compounds of the cited references. Applicant submits that claim 1 is distinct and unobvious over claims 1 - 12, and 14 of US Patent No.6,410,550 in view of Albaugh et al. (WO 99/10347) as the pharmaceutical formulation of claim 1 is not produced by this combination as suggested by the Examiner. Applicant submits instant claim 1 is therefore patentable under the cited judicially created doctrine of obviousness-type double patenting and respectfully requests withdrawal of the rejection.

Applicant in addition submits that claims 2, 8, as currently amended, and 9 - 12 all of which incorporate the novel and unobvious features of claim 1, are all patentable under the cited judicially-created doctrine of obviousness-type double patenting over the cited references, either separately or in the combination cited by the Examiner, and respectfully requests withdrawal of the rejection.

Applicant submits that the above arguments apply equally to currently amended claim 3 which also recites "...estrogen, selective estrogen modulators, or vitamin E...," and is not a mere combination of the compounds of the cited references. Thus, claim 3 is patentable under the judicially-created doctrine of obviousness-type double patenting, and currently amended claims 4 - 7 and new claims 17 - 22 which depend directly or indirectly on claim 3, and incorporate the novel and unobvious features of claim 3, are therefore all patentable under the judicially-created doctrine of obviousness-type double patenting. Applicant respectfully requests withdrawal of the rejection of claims 3 and 4 - 7 and 17 - 22.

Rejection under 35 USC § 112, second paragraph

The Examiner rejected claims 3 - 8 under 35 USC § 112, second paragraph, for indefiniteness. With regard to claim 3, the Examiner specifically refers to the recitation of "less than -5%; greater than 5%". Applicant respectfully submits that claim 3 recites "-5%" in connection with the functional efficacy of $\alpha 1$ and/or $\alpha 5$ receptor subtypes and "greater than 5%" in connection with the functional efficacy $\alpha 2$ and $\alpha 3$ receptor

subtypes. Applicant submits the values recited are for separate receptors and claim 3 therefore does not recite a narrow range that falls within a broad range. Without prejudice, and in the interests of facilitating prosecution, applicant has amended claims 3 - 7 by deleting the phrases which included the term "preferably" and a value and reciting the deleted preferred values in claims 17 - 22 that depend directly or indirectly on claim 3. Applicant submits currently amended claims 3 - 7 and new claims 17 - 22 are all patentable under 35 USC § 112, second paragraph, and respectfully requests withdrawal of the rejection.

With regard to claim 8 the Examiner states that it is unclear what the term "members" represents in the recital of "from 3 - 7 members" in lines 10 - 11, at page 37. Applicant respectfully refers the Examiner to original claim 8 which recited "...X represents a carbocyclic group ... containing from 3 – 7 members, up to two of which are optionally hetero atoms selected from oxygen and nitrogen..." Applicant notes that the term "members" clearly refers to the carbon atoms forming the carbocyclic group. However, to facilitate prosecution, applicant has replaced the term "members" with the term "atoms," and respectfully requests withdrawal of the rejection.

Further with regard to claim 8 the Examiner states "the term "lower" (as used in the term "lower alkyl") is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree...." Applicant respectfully refers the Examiner to page 22, line 5 of the instant specification, where the term "lower alkyl" is defined in detail. Applicant submits that use of the above term is within the lexicon as defined by applicant and submits that the instant use of the term does not render the claim indefinite under 35 USC § 112, second paragraph, and respectfully requests withdrawal of the rejection.

Also with regard to claim 8, the Examiner states that in the recital of "where each alkyl may be optionally substituted..." it is unclear as to whether "substituted" is actually in the claims. Without prejudice, and in the interests of facilitating prosecution, applicant has amended claim 8 to recite "...wherein each lower alkyl may be optionally substituted..." Applicant submits claim 8, as currently amended, is patentable under 35 USC § 112, second paragraph, and respectfully requests withdrawal of the rejection.

Rejection under 35 USC § 103(a)

The Examiner rejected claims 1 - 12 under 35 USC § 103(a), as being unpatentable over Albaugh et al. (WO 99/10347) and Coe et al. (WO 99/35131). The Examiner concedes that "The cited references do not expressly teach a pharmaceutical composition comprising both $GABA_A$ and NRPA."

Applicant submits that instant claim 1 recites: "A pharmaceutical composition comprising a combination of an inverse agonist of the $GABA_A$ $\alpha 5$ receptor subtype; a nicotine receptor partial agonist (NRPA), estrogen, selective estrogen modulators, or vitamin E; and a pharmaceutically acceptable carrier."

Applicant further submits that neither of the cited references teach suggest or hint that they be combined to form a pharmaceutical composition comprising both $GABA_A$ and NRPA, let alone the pharmaceutical composition of instant claim 1 which in addition comprises "...estrogen, selective estrogen modulators, or vitamin E...," and is therefore not a mere combination of the compounds of the cited references. Applicant submits claim 1 is patentable under 35 USC § 103(a) over the cited references, as they do not produce the pharmaceutical formulation of instant claim 1 either separately or in the combination cited by the Examiner, and respectfully requests withdrawal of the rejection.

Applicant in addition submits that claims 2, 8, as currently amended, and 9 – 12, all of which incorporate the novel and unobvious features of claim 1, are all patentable under 35 USC § 103(a) over the cited references, either separately or in the combination cited by the Examiner, and respectfully requests withdrawal of the rejection.

Applicant submits that the above arguments apply equally to claim 3, as currently amended, which also recites "...estrogen, selective estrogen modulators, or vitamin E...," and is therefore not a mere combination of the compounds of the cited references and is therefore patentable under 35 USC § 103(a) over the cited references, and to currently amended claims 4 - 7 and new claims 17 - 22 which depend directly or indirectly on claim 3, and incorporate the novel and unobvious features of claim 3, and are therefore are all patentable under 35 USC § 103(a). Applicant respectfully requests withdrawal of the rejection of claims 3 and 4 - 7 and 17 - 22.

In view of the amendments set forth herein and remarks above, the applicant respectfully submits that the pending claims are fully allowable, and solicits the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact applicant's undersigned attorney at the telephone number provided.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§1.16 and 1.17 or to credit any overpayment to Deposit Account No. 16-1445.

Date: June 9, 2003

A. David Joran
Attorney for Applicant(s)
Reg. No. 37,858

Pfizer Inc
Patent Department
150 East 42nd Street – 5th Floor
New York, NY 10017-5755
(212) 733-3381